

I have two very general comments on the Draft Interim Guidance on Financial Relationships (besides noting that this draft is a welcome and very important step forward, and pointing out that it needs a good editor):

(1) The draft appears to consider clinical investigators as the only study personnel potentially affected by financial conflicts of interest. As this is clearly not true, it would be preferable if the draft addressed the possibility that study coordinators and others working under the authority of the principal investigator may also have conflicts, and suggest ways to address those-either independently of the PI or by noting that the PI is responsible for the actions of those working under his/her authority, and therefore responsible if conflicts compromise subject safety or decisionmaking.

(2) This draft, like everything else on the subject, addresses only FINANCIAL conflicts of interest. While granting that \$ issues are more easily addressed than the broader category sometimes called "conflicts of commitment," it is in my view strikingly important that some acknowledgment be made that not-directly-financial factors such as prestige, recognition by peers, academic advancement, or even just being seen as a "team player" may have substantial effects on the good conduct of research that are indistinguishable from the effects of financial COI. One has only to recall that Jim Wilson was quoted in the NYTimes as saying [i'm paraphrasing but this was the gist] that he was offended by everyone's belief that he was in it for the money, since what mattered to him was the academic prestige, the hoped-for awards-in short, the glory. In his view, and I assume he thought readers would share it, being out for money is unacceptable, but being out for glory is not. Certainly it is true that managing this type of conflict is a much more difficult challenge, and perhaps can only be accomplished by general and less direct avenues like improved research ethics education and professional socialization, and greater care in ensuring that research design and implementation are carefully monitored to maximize subject safety and informed decisionmaking. But at the very least, non-financial conflicts should be acknowledged to exist and to pose risks to subjects when not addressed.

Thank you for the opportunity to comment.

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